

REMARKS

In this Amendment, Applicant has cancelled Claim 4, and amended Claims 1 and 7 – 9 to specify different embodiments of the present invention and overcome the rejection. It is respectfully submitted that no new matter has been introduced by the amended claims. All claims are now present for examination and favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

REJECTION UNDER 35 U.S.C. § 101:

Claim 8 has been rejected under 35 U.S.C. § 101 as allegedly failing to define a patentable subject matter.

It is respectfully submitted that in view of the currently presented amendments, the rejection has been overcome. More specifically, Claim 8 has been amended to method claims including specific and positive step(s).

Therefore, the rejection under 35 U.S.C. § 101 has been overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. § 101 is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 112 SECOND PARAGRAPH:

Claim 8 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is respectfully submitted that the amended Claim 8 clearly points out and defines the embodiment of the present invention. More specifically, the specific step of “utilizing” has been added.

Therefore, the rejection under 35 U.S.C. § 112, second paragraph, has been overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested.

REJECTIONS UNDER 35 U.S.C. §102:

Claims 1 – 4 and 7 have been rejected under 35 U.S.C. §102 (b) as allegedly being anticipated by Ferrari (US 6,355,270). Claims 1, 3 – 7 and 9 have been rejected under 35 U.S.C. §102 (a/e) as allegedly being anticipated by Thormar (US 6,396,763).

Applicant traverses the rejection and respectfully submits that the embodiments of present-claimed invention are not anticipated by Ferrari or Thormar. At first, Claim 1 has been amended to specify that the acrylic acid containing polymer is a hydrogel. In addition, the composition defined in presently amended Claims 1 – 3, 5 – 7 and 9 as well as the method in Claim 8 are different from the composition or method disclosed or suggested in Ferrari or Thormar.

Ferrari teaches a particle for oral delivery of a bio-polymeric drug wherein bio-polymeric means polypeptide, protein, polynucleic acid (col. 1, lines 44 – 45 of Ferrari). The particle has a **solid** substrate with front and back faces. Indeed, the method for producing the drug delivery particles includes a **sheet** of particle-forming material forming a **reticular lattice pattern** (col. 2, lines 20 – 21 of Ferrari, emphasis added). The biopolymer drug is filled in the pores of such particles' substrate (col. 3 lines 22) and said biopolymeric drug may be gm-csf. (col. 1, lines 56 – 58 of Ferrari).

These features are completely different from the present invention wherein the acrylic acid containing polyer is a gel particularly hydrogel and not a solid substrate. The chemoattractant is mixed with the gel (Example 2 at paragraph 37 of the published specification of the present application) and not filled in a lattice. Moreover, the gel of the present invention is at a pH of 6 or less, which preserves the bioactivity of the chemoattractant such as Gm-csf (paragraph 21 of the published specification of the present application).

Further, Ferrari teaches a composition of drug-delivery particles with an enteric coating material that encapsulates the particles (col. Lines 11 – 14). It is this enteric coating material that dissolves at a pH of 6-6.8. Such pH is the intestine pH used to dissolve the coating (col. 6 lines 45 – 50).

To the contrary, in the present invention, no encapsulation of the chemoattractant is used and pH 6 or less is the drug composition pH (page 2, paragraphs 21 – 22 of the published specification of the present application). Such pH surprisingly conserves the bioactivity of the chemoattractant such as Gm-csf. Therefore, Ferrari does not anticipate the present invention as defined.

On the other hand, Thormar fails to disclose a composition as defined in the present invention at pH 6 or less. In fact, Applicant has not found at col. 6 line 40 any reference to pH composition. In addition, Fig. 3 discloses the effect of receiver fluid pH on release profile of monocaprin (a lipid) from formulation 1R. Monocaprin is not a chemoattractant but a lipid.

Moreover, pH 6 or less is not the pH of formulation 1R, but the pH of a receiver phase after a membraneless diffusion test. Again, this has nothing to do with a composition comprising an acrylic acid containing polyer and a chemoattractant at a pH of 6 or less.

It is respectfully submitted that neither Ferrari nor Thormar teach or suggest the invention as claimed and the composition and method contained in the present application are not identical or similar to those disclosed in the cited references.


Therefore, the rejection under 35 U.S.C. § 102 has been overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. § 102 is respectfully requested.

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,

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